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**Declarations under Rule 4.17:**

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations* AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

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(54) Title: ORAL PHARMACEUTICAL PREPARATION COMPRISING A PROTON PUMP ANTAGONIST AND A BASIC EXIPIENT

(57) Abstract: The invention relates to novel dosage forms for proton pump antagonists.

WO 2004/089342 A3

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61K9/20 A61K31/4439 A61K9/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/45693 A (BYK GULDEN LOMBERG CHEM FAB ; LINDER RUDOLF (DE); NEY HARTMUT (DE); DI) 13 June 2002 (2002-06-13) cited in the application page 44, line 9 - page 46, line 6 examples 27-29 page 40, paragraph 5 page 41, paragraph 2 page 42, paragraph 3 example N	1-26
X	DE 199 25 710 A (BYK GULDEN LOMBERG CHEM FAB) 14 December 2000 (2000-12-14)	1-16, 22-26
Y	column 3, line 40 - line 63 column 4, line 23 - line 28 column 4, line 60 - line 68 examples column 5, line 18 - line 25	17-21
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

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- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*&\* document member of the same patent family

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/74654 A (BYK GULDEN LOMBERG CHEM FAB ; LINDER RUDOLF (DE); DIETRICH RANGO (DE)) 14 December 2000 (2000-12-14)	1-16, 22-26
Y	page 6, paragraph 6 - page 7, paragraph 4 examples	17-21
X	US 2002/045646 A1 (PHILLIPS JEFFREY O) 18 April 2002 (2002-04-18)	1-16, 22-26
Y	paragraphs '0036!, '0037!, '0085! - '0090!, '0278!, '0394!, '0398! - '0403!, '0418! - '0432!, '0436! - '0446! Tablet D3, example I table 8	17-21
P,X	US 2004/028737 A1 (DESHMUKH SATISH RAMACHANDRA ET AL) 12 February 2004 (2004-02-12) examples 3,4	1-16, 22-26
X	EP 1 222 922 A (EISAI CO LTD) 17 July 2002 (2002-07-17)	1-16, 22-26
Y	examples 4-8; table 2	17-21
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Y	column 6, line 65 - column 7, line 34 example 5	17-21
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Y	examples 9,10	17-21
X	WO 98/50019 A (CHEN JIVN REN ; SAGE PHARMACEUTICALS INC (US)) 12 November 1998 (1998-11-12)	1-16, 22-26
Y	examples	17-21
X	WO 00/78284 A (LAHAV RAFFAEL ; AZOULAY VALERIE (IL); DEXCEL LTD (IL)) 28 December 2000 (2000-12-28)	1-16, 22-26
Y	examples 1,4,10,13	17-21

# INTERNATIONAL SEARCH REPORT

ational application No.  
PCT/EP2004/050493

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 1-26 partly  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 1-26 partly

Present independent claim 1 relates to an extremely large number of possible oral dosage forms, namely all those comprising: 1) a reversible PPI ("proton pump antagonist" or APA), and 2) a basic excipient, with no restriction or limitation, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such dosage forms, namely film-coated immediate release tablets comprising soraprazan (as defined in claim 18) and a basic compound as defined in claims 15 and 16. Other possibilities are not sufficiently disclosed in the application. In particular, it is not proved that the stabilising effect is also achieved for other APAs different from soraprazan. The area covered by the claims is broader than justified by the extent of the disclosure. It follows that the claims so lack support, and/or the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. It is the same for independent claims 22 and 23.

Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the dosage form by reference to the result to be achieved, expressed in terms of parameters (disintegration rate; see claims 3, 6-10 and 23-25), which only amounts to claiming the technical problem to be solved instead of claiming the relevant technical features which amount to its solution. This lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to claim 1 taken in combination with claims 5, 15 and 16, and 18, as interpreted in connection with the description and the examples.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

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